

Date: August 16, 2023

Memorandum regarding Health Canada's REB Attestation Form (REBA)

An REB may use its own letter of attestation in lieu of the REBA form provided by Health Canada. If a REB uses its own letter, it should explain how the REB complies with the membership requirements for REBs defined in the applicable *Regulations* and must attest to the following 2 points:

- The REB carries out its functions in a manner consistent with GCPs; and
- The REB has reviewed and approved the clinical trial protocol and ICD for the trial which is to be conducted by the qualified investigator named on the attestation for the specified clinical trial site. The approval and the views of the REB have been documented in writing

These requirements can be satisfied by the HiREB approval letter, regardless of whether it is issued through the local eREB system or CTO Stream:

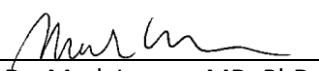
- The compliance attestation paragraph in the approval letter specifies that “HiREB operates in compliance with and is constituted in accordance with ... The International Conference on Harmonisation of Good Clinical Practices Guideline (ICH GCP)... The Food and Drug Regulations, Natural Health Products Regulations, Medical Devices Regulations...”
- The approval letter contains the study name, along with the document name and version date/number for the protocol and consent form documentation. The LPI is named on the approval letter, as are the participating sites to which the approval applies. The approval letter itself is the written documentation.

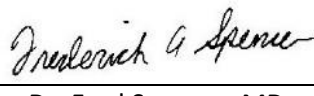
For studies conducted with the Natural and Non-prescription Health Product Directorate, the HiREB membership list indicates the name and qualifications of the REB member who is knowledgeable in complementary or alternative health care.

HiREB will no longer sign Health Canada REB Attestation form (REBA) for REB approvals issued after December 01, 2022 (as is already the case at other Ontario academic hospitals and specialized REBs). Should Sponsors/CRO request that a REBA be completed for a letter sent after this date, please provide a copy of this memorandum. Requests for REBAs for letters sent prior to this date can be sent to hireb@hhsc.ca.

Should there be any questions, please do not hesitate to contact:

Erin Bell, HiREB Manager
Email: belle@hhsc.ca
Phone: 905 521-2100 Ext 42013


Dr. Mark Inman, MD, PhD.
Chair, HiREB


Dr. Fred Spencer, MD
Chair, HiREB


Ms. Erin Bell, M.Sc.
Manager, HiREB